

REMARKS/ARGUMENTS

Claim 1 stands rejected by the examiner as allegedly obvious over Utsumi (U.S. Patent 4,005,200) in view of Blum et al (Gynecol. Obstet. Invest. 15:10-15, 1983) and Rodriguez (U.S. Patent 6,511,970). The examiner argues (1) that Utsumi establishes the use of estrogen and DHEA against vaginal dryness (in view of Blum), and (2) that Rodriguez suggests substitution of SERMs for the estrogen of Utsumi. Applicant respectfully traverses the obviousness rejection for the following reasons.

First, it is not believed that Utsumi discloses the combination of estrogen and DHEA for treating vaginal dryness. Utsumi mentions "various" syndromes associated with climacterium (Col. 1; lines 67-68), implying that Utsumi's combination might be useful in some but not all such syndromes, without specifying which. The Blum reference, mentions vaginal dryness as a climacteric symptom, but expressly notes that its list of four such symptoms are "only but few" of the many such symptoms that exist (Abstract, line 2). Blum thus makes it even less likely that Utsumi is talking about vaginal dryness. Utsumi also falls short of showing effectiveness of the combination of DHEA and estrogen because it uses a DHEA ester that Utsumi merely speculates (without proof) might act through a DHEA-mediated mechanism. Even as to the DHEA esters, Utsumi states only that "[i]t has been proposed" to use the combination of DHEA ester and estrogen - - not that such combination had actually been used, or shown to be effective. For all of these reasons, it is believed that Utsumi and Blum do not suggest DHEA in combination with estrogen for treating vaginal dryness.

Second, even if Blum and Utsumi had together established that estrogen and DHEA in combination would be a useful treatment of vaginal dryness (and this is not believed to have been established for the reasons given above), the Rodriguez reference fails to suggest substituting SERM for estrogen to arrive at applicant's claimed invention. SERMs (Selective Estrogen Receptor Modulators), as their name implies, function as estrogen receptor antagonists in some tissues while providing estrogen or estrogen-like effect in other tissues. Rodriguez states a preference for antagonistic activity in ovarian epithelium and other tissues (Col 41; lines 3-8), and suggests SERMs (Col 41; lines 13-15). However, Rodriguez does not treat vaginal dryness, and does not disclose or suggest that SERMs may be used in place of estrogens for that purpose.

Indeed, as shown at Col 41; lines 3-8 of Rodriguez, there are many instances where SERMs behave in the opposite manner from estrogens (e.g. as antiestrogens). Without a specific discussion of vaginal dryness, Rodriguez does not suggest interchangeability of SERM and estrogen for that purpose. For all of the foregoing reasons, it is urged that the obviousness rejection should be withdrawn.

It is believed that the application is now in condition for allowance. Issuance of a notice of allowance is solicited.

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